

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method of manufacturing a drug granule, comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus, wherein the drug granule has a granular strength of 650-2500 gf/mm², and wherein the drug is selected from the group consisting of metformin hydrochloride, ethydrionic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride.

2. (Cancelled)

3. (Currently Amended) A drug granule obtained by a method comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus, wherein the drug granule has a granular strength of 650-2500 gf/mm², and wherein the drug is selected from the group consisting of metformin hydrochloride, ethydrionic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride.

4. (Cancelled)

5. (Previously Presented) The drug granule of claim 3, having a particle size of 0.05 mm – 1.5 mm.

6. (Previously Presented) A pharmaceutical preparation comprising the drug granule of claim 3, and a pharmaceutical acceptable additive.

7. (Currently Amended) A coated granule obtained by a method comprising: ~~a step of~~ spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus to form a drug granule, wherein the drug granule has a granular strength of 650-2500 gf/mm² and wherein the drug is selected from the group consisting of metformin hydrochloride, ethyronic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride, and a ~~step of~~ coating said drug granule with a release control film coating agent.

8. (Cancelled)

9. (Previously Presented) The coated granule of claim 7, wherein the release control film coating agent is a sustained release agent or an enteric coating agent.

10. (Currently Amended) A method of manufacturing a coated granule, which comprises:

(a) ~~a step of~~ spraying a solution of a water soluble drug on a crystal of said water soluble drug obtained by a method comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus to form a drug granule,

wherein the drug granule has a granular strength of 650-2500 gf/mm² and the drug is selected from the group consisting of metformin hydrochloride, ethydrionic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride; and

(b) ~~a step of~~ coating said drug granule with a release control film coating agent.

11. (Cancelled)

12. (Currently Amended) A granule of a water soluble drug, which is substantially free of a binder and which has a granular strength of 650-2500 gf/mm², having a crystal of said water soluble drug in a nucleus, wherein said granule comprises a drug which is selected from the group consisting of: metformin hydrochloride, ethydrionic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride.

13. (Currently Amended) A coated granule comprising a granule of a water soluble drug, which granule comprises a crystal of said water soluble drug as a nucleus, being substantially free of a binder and having a granular strength of 650-2500 gf/mm², and a release control film coating agent coated thereon, and wherein said granule comprises a drug which is selected from the group consisting of: metformin hydrochloride, ethydronic acid di-sodium, cimetidine, carbocisteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride.

14. (Original) A coated granule comprising an inner layer comprising the drug granule of claim 12 and an outer layer comprising a release control film coating agent.